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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,840	01/17/2001	Barbara A. Zilinskas	13216-73220	8791

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/31/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,840

Applicant(s)

ZILINSKAS ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 7, filed 29 October 2002. Applicant elects Group I, claims 1-10 and 18-21, without traverse. Applicant has cancelled claims 11-17, which are drawn to a non-elected invention. After further review of the claims, it is apparent that claims 18-21 should be grouped with Group II, as they depend on Group II claims. Therefore, claims 18-21 are withdrawn as belonging to a non-elected invention.
2. Claims 1-10 are pending, and are examined in the instant application. This restriction is made FINAL.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3, filed 17 January 2001, is attached to the instant Office action.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because

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The claimed invention is directed to non-statutory subject matter. Claim 9 is drawn to seed of transgenic turfgrass. The seed is the product of segregation of alleles, and because the seed has not been raised under selective conditions, some seed will not contain the transgene(s). Rather this seed will be identical to the wild-type parent, which is a product of nature.

Claim Rejections - 35 USC § 112-second

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-10 are rejected under 35 U.S.C. 112-2nd.

In claim 1 (b),

- Virulence genes that confer "strong infectivity" to Agrobacterium is unclear because the term lacks a comparative basis. What is the "strong infectivity" relative to? Because of the unclarity of this term, no weight is given it in evaluating the prior art.
- Line 13, "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may

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recite the various components of the "gene" desired. All

subsequent recitations of the language are also rejected.

- Recites "a promoter" twice, without clear antecedent basis. Are these the same promoter, or different promoters?
- In line 14, "transformed cells operably linked" is unclear. What is operably linked? The cells? The marker?

In 1 (d), "the antibiotic" lacks antecedent basis.

In claim 7, "the turfgrass" lacks antecedent basis. "de-differentiation" is unclear.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 8 and 9 are drawn to transgenic turfgrass prepared by the method of claim 1, and seed of this plant. However, no phenotype or genotype of the plant is described, so that it would not be clear of one skilled in the art that the inventor had possession of the claimed invention at the time of filing of the specification.

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See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention"

1. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). The *Wands* factors are

- *The nature of the invention and the breadth of the claims.* Applicant's claims are drawn to a method of producing a transgenic turfgrass plant, any turfgrass, any *Agrobacterium*, any transgene selected from the group of glucose oxidase, citrate synthase, delta-9 desaturase from *S. cerevisiae* or *Cryptococcus curvatus*, delta-11 desaturase, a plant homologue to the neutrophil NADPH oxidase, bacteriopsin from *H. halobium*, and any gene encoding a pokeweed antiviral protein.
- *The state of the art.* The area of plant transformation is unpredictable (Burch, Ann. Rev. Plant Physiology and Plant Mol Biol, vol 48, pages 297-326, 1997.

page 297) with a major problem being the development of methods and constructs to produce a high proportion of plants showing predictable transgene expression without collateral genetic damage. The art is such that the skilled person can introduce genes into plant cells but that generation of a given particular phenotype is unpredictable. Gene expression levels and inheritance are unpredictable (Deroles, SC and Gardner, RC; (1998) Plant Molecular Biology 11: 355-364; Dunwell, JM and Paul, EM, 1990, Outlook on Agriculture 19, 103-109; Finnegan J and McElroy D Bio/Technology 12: 883-888, 1994). Tissue culture techniques are inherently variable and are often the limiting factor in success of transformation and regeneration of transformants.

- *The amount of guidance given, and the presence of working examples.* The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). Applicant provides three examples: Example 2, of Agrobacterium mediated transformation of Creeping Bentgrass with superbinary plasmid pSB111SH. Example 3, of Agrobacterium mediated transformation of Tall Fescue with superbinary plasmid pSB111SH. Example 4, Agrobacterium mediated transformation of Velvet Bentgrass with superbinary plasmid pSB111SH. Applicant gives detailed information about bacterial and plant media which could be used, and goes through a series of steps, beginning with production of callus from seed, and followed by steps which could result in the production of transgenic turfgrass tissue or plants. However, Applicant gives no guidance about which protocols, which media and which steps, if any, result is

the production of transgenic turfgrass plants. While working examples are not required, guidance as to what protocols, what conditions, what starting materials, and which combinations of these are required, with a reasonable expectation of success. Lacking such guidance, one skilled in the art would need to do random trial and error experimentation, which would require undue experimentation to make and/or use the claimed invention.

9. Claim 3, drawn to genes from a plasmid of *Agrobacterium tumefaciens* stain 281, and claim 4, drawn to a plasmid pSB111SH, are rejected because the specification lacks sufficient evidence that the claimed biological material is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 C.F.R. 1.801-1.809. If the claimed biological material were deposited under the provisions of the Budapest Treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest Treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of the patent. Applicant's attention is directed to 37 C.F.R. §§ 1.801-1.809, M.P.E.P. §§ 2402-2411.05 and In re Lundak, 773 F.2d. 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulations for Deposit of Biological Materials for Patent Purposes.

Applicant describes various parts of the plasmid pSB111SH, but no sequence information is given, so that one skilled in the art would not be able to reproduce this plasmid. A plasmid of *Agrobacterium tumefaciens* stain 281, the virulence genes

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thereof, has no further information given, and one skilled in the art would not be able to reproduce this plasmid

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Stalker, US 4,810,648, issued March 7, 1989.

Stalker teaches the production of transgenic turfgrass (col 6, lines 65-69) by providing regenerable callus tissue (col 6, line 69), inoculating the tissue with Agrobacterium (col 21, lines 43-45) having a heterologous DNA construct linked to a promoter from a monocot species (col 6, lines 38-42) and a antibiotic resistance selectable marker (col 19, lines 55-58), culturing under conditions to enable the Agrobacterium to transform cells of the tissue (col 21, line 36-55), selectively culturing on antibiotic (col 22, lines 63-65), and producing transgenic turfgrass (col 6, lines 63 – col 7, line 2).

Accordingly, Stalker anticipates the claimed invention.

Because of the lack of clarity about "strong infectivity" and "the promoter", these limitations are given no weight.

Remarks

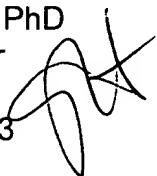
3. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Group 1638
January 10, 2003




ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600